REMARKS

I. INTRODUCTION

Prior to entry of the current amendment, claims 1, 3-5 and 7-10 are pending in the present application. Claims 1, 3-5 and 7-10 stand rejected under 35 U.S.C. § 103(a). By the present amendment, claims 1, 4, 5, 8 and 9 have been amended, and claims 3 and 7 have been canceled without prejudice. No new matter has been added by the current amendment, as support thereof can be found in the present specification at, *inter alia*, page 3, lines 20-21; and originally filed claims 3 and 7. Applicant respectfully submits that the pending claims are now in condition for allowance.

II. REJECTIONS UNDER 35 U.S.C. §103 (a)

Claims 1, 3, 5, 7 and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,466,888 ("Verkaart") in view of U.S. Patent No. 5,472,605 ("Zuk, Jr.") and U.S. Patent No. 5,607,830 ("Biesel *et al.*"). In addition, claims 4, 8 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Verkaart in view of Zuk, Jr. and Biesel *et al.* as applied to claim 1, 3, 5, 7 and 9 above, and further in view of U.S. Patent No. 5,643,193 ("Papillon *et al.*"). Applicant respectfully submits that these rejections should be withdrawn for at least the following reasons.

In order for a claim to be rejected for obviousness under 35 U.S.C. § 103(a), not only must the prior art teach or suggest each element of the claim, but the prior art must

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also suggest combining the elements in the manner contemplated by the claim. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F. 2d 931, 934 (Fed. Cir. 1990), *cert. denied* 111 S.Ct. 296 (1990); *In re Bond*, 910 F. 2d 831, 834 (Fed. Cir. 1990). The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *See* M.P.E.P. §2142. To establish a *prima facie* case of obviousness, the Examiner must show, *inter alia*, that there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references and that, when so modified or combined, the prior art teaches or suggests all of the claim limitations. *See* M.P.E.P. §2143. Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness.

Verkaart is directed to a suction liquid collection assembly and flexible collecting bag therefor. According to Verkaart, the collection assembly includes "a disposable, flexible liner ... positioned within a vacuum chamber ... [wherein] the vacuum chamber is readily sealed despite the inlet ports to the disposable bag." Verkaart, col. 2, lines 12-17. Verkaart discloses a blood collection bag which is positioned between two shells, wherein the bag includes a particulate material filter which divides the bag into two chambers. *See* Verkaart, col. 2, lines 55-57; col. 3, lines 59-61; figs. 1, 4-5. According to Verkaart, "[t]he filter lies substantially flat between the front and rear faces of the bag when the bag is collapsed," as "[t]he filter is heat sealed to the front face of the bag along a top edge 72 and it is heat sealed to the rear face of the bag along an edge 74." Verkaart, col. 2, lines 57-59; col. 5, lines 7-9.

Zuk, Jr. is directed to a liquid filtration device useable for removal of leukocytes and other blood components. Zuk, Jr. discloses a device including "a first chamber which is in fluid flow relationship with a second chamber. Filtration elements separate the first chamber from the second chamber so that liquid flowing from the first chamber is filtered thereby prior to entry into the second chamber. A passage leads from the second chamber into the first chamber and a hydrophobic filter may be used to prevent liquid from the first chamber from flowing through the passage into the second chamber while allowing air to flow therethrough. An outlet is located in the second chamber, preferably at the bottom thereof." Zuk, Jr., abstract.

Biesel *et al.* is directed to a method for the continuous conditioning of a cell suspension. According to the method and apparatus disclosed in Biesel *et al.*, "the cell suspension is centrifuged and the separated components of the cell suspension are separately removed." Biesel *et al.*, col. 1, lines 11-13. As previously described in the Response to the Office Action mailed on March 28, 2003, the current specification has been amended to incorporate Biesel *et al.* (U.S. Patent No. 5,607,830) by reference, which is the U.S. equivalent of the previously cited German Patent No. 42 26 974.

Papillon *et al.* is directed to an apparatus for the collection, washing and reinfusion of shed blood. According to Papillon *et al.*, the number of components and steps needed to collect, wash and reinfuse blood is reduced in the apparatus of Papillon *et al.* "by

modifying the centrifuge bowl and locating it between the surgical site and the vacuum source." Papillon *et al.*, col. 2, lines 63-64. The apparatus of Papillon *et al.* includes a tube 10 for collecting blood from a surgical site, connected via a coupling 11 to an aspiration line 12 which "connects to the inlet port 22 of a centrifuge bowl 25, which is itself part of a centrifuge apparatus 24 that comprises the bowl 25 and means for rotating the bowl which are not shown." Papillon *et al.*, col. 4, lines 7-10. According to Papillon *et al.*, a vacuum source 34 applies negative pressure thereby drawing blood from the surgical site into tube 10, coupling 11, and aspiration line 12, where the blood then "enters input port 22 and passes through the filter 42 into the separation chamber 48 of centrifuge bowl 25, which is rotating at about 2000 to 3000 rpm." Papillon *et al.*, col. 4, lines 61-63.

In contrast to the teachings of Verkaart in view of Zuk, Jr. and Biesel *et al.*, and further in view of Papillon *et al.*, the autotransfusion set of the present invention, as currently recited in independent claims 1 and 5 in amended form, includes "a filter means for eliminating at least one of leukocytes and tumor cells," and "a blood collecting tank having an inlet and an outlet," "wherein the filter means is arranged *in the blood collecting tank*" (emphasis added). Likewise, the method of the present invention, as currently recited in independent claim 9 in amended form, includes the claim limitation of "passing the blood through a blood supply line including ... a filter arranged *in the blood collecting tank*, ... [and] passing the blood through the filter to eliminate at least one of leukocytes and tumor cells."

In accordance with the present invention, and as described in the current specification, "[l]eukocytes and/or tumor cells can be eliminated in principle before or after processing the blood. However, eliminating the leukocytes before processing reduces the quantity of products of leukocyte activation or traumatization of the blood product for transfusion. Therefore, the filter for elimination of leukocytes and/or tumor cells is preferably arranged in the blood supply line leading to the separation unit of the autotransfusion set." Specification, page 3, lines 1-8.

Furthermore, in accordance with the present invention, as currently recited in the pending claims, the filter for eliminating leukocytes and/or tumor cells is arranged in the collecting tank, which is also known as a cardio reservoir. "This is advantageous inasmuch as no separate filter housing is needed. Providing the leukocyte depletion filter in the collecting tank not only eliminates the need to provide a separate filter housing but also prevents the risk of leakage due to additional connecting parts. The filter for eliminating leukocytes and/or tumor cells may be arranged in the collecting tank together with the filter which is preferably generally provided with the known cardio reservoir to remove particulate impurities. To this extent, the manufacturing cost is low." Specification, page 3, lines 14-23.

Thus, Verkaart in view of Zuk, Jr. and Biesel *et al.*, and further in view of Papillon *et al.*, do not teach nor suggest an autotransfusion set including "a filter means for eliminating at least one of leukocytes and tumor cells," and "a blood collecting tank having an inlet and an outlet," "wherein the filter means is arranged in the blood collecting tank."

Likewise, Verkaart in view of Zuk, Jr. and Biesel *et al.*, and further in view of Papillon *et al.*, do not teach nor suggest a method of autologous blood transfusion including "passing the blood through a blood supply line including ... a filter arranged in the blood collecting tank, ... [and] passing the blood through the filter to eliminate at least one of leukocytes and tumor cells." Therefore, Verkaart in view of Zuk, Jr. and Biesel *et al.*, and further in view of Papillon *et al.*, do not disclose nor suggest each and every element of the presently claimed invention, and thus Applicant respectfully submits that the rejections based on these patents should therefore be withdrawn.

Although the Examiner has alleged that "it would have been obvious to one of ordinary skill in the art to modify Verkaart's device to include a filter capable of removing toxins such as leukocytes given Zuk[, Jr.]'s teaching that this is old and well known in the art," (Office Action mailed 9/22/04, pages 3-4, paragraph 6), Applicant respectfully disagrees in regard to the pending claims. That is, as admitted by the Applicant in the current specification, leukocyte depletion filters are known in the art. *See* specification, page 2, lines 7-16. However, there is no teaching, suggestion, nor motivation in the prior art, or in any of the cited patents, to produce an autotransfusion set including a filter means for eliminating at least one of leukocytes and tumor cells, wherein the filter means is arranged in a blood collecting tank, or to produce a method of autologous blood transfusion including passing blood through a filter to eliminate at least one of leukocytes and tumor cells, wherein the filter is arranged in a blood collecting tank. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests

the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

For at least the preceding reasons, Applicant respectfully submits that the rejections of the pending claims under 35 U.S.C. § 103(a) have been overcome and should therefore be withdrawn.

III. CONCLUSION

Applicant respectfully submits that the pending claims are in condition for allowance and requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicant's attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,
KENYON & KENYON

Dated: December 22, 2004

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